DETAILED ACTION

1. Applicant's amendments to the claims, filed on January 4, 2010, are acknowledged.

Claims 1-16 and 43-49 have been canceled.
Claims 17-42 and 50-63 are pending.

Claims 58-60 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 4, 2009.

Claims 17-42, 50-57, and 61-63 are currently under consideration as they read on the elected anti-CD22 antibody comprising CDRs of SEQ ID NOs: 7, 11-14, 16, the VL chain of SEQ ID NO:20 and the VH chain of SEQ ID NO:21.

2. This Office Action will be in response to applicant's arguments, filed on January 4, 2010.

The rejections of record can be found in the previous Office Action, mailed on October 5, 2009.

3. Following references have been cited by applicant in the Remarks filed on January 4, 2010. These references have been listed on PTO-892 and copies of the references are not provided herein.

US Patent 5,602,095
US Patent 5,608,039
US Patent 4,892,827.
Mansfield et al. Blood. (1997) 90:2020-2026.
Pai et al. PNAS (1991) 88:3358-3362.

Kondo et al. JBC (1988) 263:9470-9475.

Debinski et al. Bioconj. Chem. (1994) 5:40-46.

4. In view of applicant's amendment to the claims, only following objection and rejections are maintained.

5. Claims 50-57 are objected to for following reasons:

Independent claim 50 recites "A method of inhibiting growth of a CD22+ cancer cell by contacting said cell with a chimeric molecule". Applicant is suggested to amend the preamble to "A method of inhibiting the growth of a CD22+ cancer cell, wherein said method comprising contacting said cell with a chimeric molecule" for clarity.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 35, 36, 41, 42, 56, and 57 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The prior Office Action states:

"Claims 35, 41, 42, 56, and 57 are indefinite in the recitation of "PE35, PE38, PE38KDEL, PE40, PE4E, and PE38QQR" because their characteristics are not known. The use of "PE35, PE38, PE38KDEL, PE40, PE4E, and PE38QQR" as the sole means of identifying the claimed mutated Pseudomonas exotoxin A renders the claims indefinite because the terms are merely laboratory designations which do not clearly define the claimed products, since different laboratories may use the same designations to define completely distinct biological materials."

Applicant's arguments, filed on January 4, 2010, have been fully considered but have not been found persuasive.

Applicant argues that the recited mutated PEs are described in the instant specification and cited references (see listed of references cited by applicant above). Thus, applicant asserts that the mutated PEs are known in the art.

This is not found persuasive for following reasons:

Contrary to applicant's assertion, it is noted that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Here, the terms (e.g. PE35) used to define the claimed *mutated Pseudomonas exotoxin A* would render the claims indefinite for reasons of record.

The attempt to incorporate subject matter of the mutated PE into this application by reference to the US Patents and NPL references cited in the Remarks (filed on January 4, 2010) is improper for reasons stated below. In addition, not all of the US Patents and NPL references relied upon by applicant used the same terms as claimed to define the mutated PE molecules. For example, the paragraph [0158] of the instant specification discloses that US Patent 5,512,658 describes PE4E. However, a search of the US Patent 5,512,658 does not show that the term PE4E was used to describe mutated PE molecule in the patent.

Therefore, the use of "PE35, PE38, PE38KDEL, PE40, PE4E, and PE38QQR" as the sole means of identifying the claimed mutated *Pseudomonas exotoxin* A renders the claims indefinite. Applicant's arguments have not been found persuasive.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 35, 36, 41, 42, 56, and 57 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record.

Applicant's arguments, filed on January 4, 2010, have been fully considered but have not been found persuasive.

Applicant argues that the claimed mutated PEs were known in the prior art and disclosed on paragraphs [0157]-[0161] of the specification. Applicant further asserts that the position 490 that being mutated in the claimed PE mutants are relative to the native PE sequence of SEQ ID NO:24. Thus, applicant asserts that one of skill in the art would know how to make the claimed mated PEs.

This is not found persuasive for following reasons:

Applicant appears to attempt to incorporate essential material of "PE35, PE38, PE38KDEL, PE40, PE4E, and PE38QQR" in the specification by reference to patents and/or to NPL references {e.g. US Patent 5,602,095, Patent 5,608,039, and US Patent 4,892,827 as well as NPL Mansfield et al. Blood. (1997) 90:2020-2026; Pai et al. PNAS (1991) 88:3358-3362; Kondo et al. JBC (1988) 263:9470-9475; and Debinski et al. Bioconj. Chem. (1994) 5:40-46}.

The incorporation of essential material in the specification by reference to a patent and/or to a publication is improper. An application as filed must be complete in itself in order to comply with 35 U.S.C. 112. See MPEP 608.01.

Further, applicant is reminded that to incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where the material is found in the various documents. See Advanced Display Systems, Inc. v. Kent State Univ., 54 USPQ2d 1673 (Fed. Cir. 2000) citing In re Seversky, 177 USPQ 144, 146 (CCPA 1973). Here, the specification fails to clearly indicate where the material

is found in the various US Patents and NPL references. For example, the specification discloses that PE4E is found in US Patent 5,512,658 and 4,895,827. However, upon review of these two US Patents, it is noted that PE4E is not disclosed in the Patents. Therefore, applicant's arguments regarding the essential materials of the mutant PEs relying upon the US Patents and NPL documents are not persuasive.

Therefore, the rejection is maintained for reasons of record.

10. Claims 17-34, 37-40, 50-55, and 61-63 are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Ram Shukla can be reached 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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TC 1644

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